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TITLE OF THE INVENTION

**PROTECTIVE CUSHION AND COOPERATIVELY
ENGAGEABLE HELMET CASING FOR ANESTHETIZED PATIENT**

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ABSTRACT OF THE DISCLOSURE

A protective helmet apparatus of modular construction to be worn by anesthetized patients for facial support during surgery . The helmet apparatus is assembled using one of a plurality of interchangeable, substantially transparent helmet casings, which are removably attachable to a plurality of dismountable facial cushions providing even support to the facial surface of a patient. The removable facial cushions are dimensioned on an interior surface to accommodate different sized facial structures of different patients to yield maximum pressure diffusion on the face and chin of the patient and are replaceable when worn. The exterior surface of the facial cushions are dimensioned for cooperative engagement with the interior surface of the helmet casing. A plurality of different facial cushions and helmet casings are modular in design and dimension to be interchangeable with each other thus providing accommodation of the broad differences in facial structure and size of patients using them for surgery. The cushions may be marked with printed or color coded indicia to designate size. A view of the patient's eyes and surrounding area is afforded through in line ocular apertures extending around a front surface area and up at least one sidewall. The ocular aperture is in line with a cushion ocular aperture when the cushion is engaged with the casing thereby allowing a view of the patient's eye and surrounding face through the ocular aperture from the side of the device. Additional utility is provided by variable elevation above a registered engagement with a mount

which also may provide a mirrored surface to reflect the patent facial features for viewing by upright doctors and operating staff. An optional integral heating element aids in temperature control of the patient's head during surgery.

1 PROTECTIVE CUSHION AND COOPERATIVELY
ENGAGEABLE HELMET CASING FOR ANESTHETIZED PATIENT

> This is a continuation-in-part of application No. 09/080,975,
filed 05/19/1998.

6 BACKGROUND OF THE INVENTION

1. Field of the Invention

11 The present invention relates to a safety helmet for
cranial protection. More particularly it relates to a modular
helmet apparatus constructed of interchanging cooperative
11 components of differing sizes which provide a prophylactic
cushion and helmet to be worn by patients undergoing general
anesthesia to prevent eye, skin, or other nerve damage from
prolonged pressure upon areas of the head as well as to
provide a safer manner for cranial manipulation during
16 surgery.

2. Prior Art

Surgeries upon patients in the prone position present a
number of patient care challenges to the anesthesiologist and
surgical staff. Once a patient undergoing a surgery requiring
21 general anesthesia is anesthetized, that patient is
essentially in a coma like state. In such a state, noxious
stimuli to the patient's body and skin, such as pressure or
pain, which would normally cause an awake patient to move to
relieve the stimulus, no longer causes such a reaction.

26 Consequently, patients under general anesthesia are especially
threatened by a number of factors, other than the surgery
itself, which arise during such surgical procedures.

1 One hazard which requires constant vigilance by the
surgical staff to protect against injury is the threat of eye
damage. Inadvertent pressure upon the ocular structures of a
patient for just a matter of minutes can cause extreme damage
or blindness to the eye. As noted above, because the
6 anesthetized patient is in a coma like state, the discomfort
of facial compression upon the eye, which would normally cause
an awake patient to move and relieve that pressure, fails to
alert the anesthetized patient. Care must be taken by an ever
alert surgical staff to inspect for possible pressure points
11 about the ocular structures of the patient and to move the
patient's face to prevent eye damage.

Other compression injuries can occur to the anesthetized
patient's forehead and chin areas. Here again, the constant
pressure upon those areas, caused by the weight of the
16 patients own head, if not relieved by movement of the face to
allow blood flow thereto, can cause localized ischemia to the
chin and forehead area. Since the anesthetized patient does
not react to the body's cues of discomfort preceding injury,
the risk of harm in a matter of minutes to these areas is
21 great.

An additional concern during surgical procedures of the
anesthetized patient is the decrease in body temperature that
can occur during surgery. Currently bulky warmed towels and
electric blankets are used in an attempt to warm the patient.
26 Such endeavors crowd the operating field and are not easily

1 controlled for temperature.

Currently, there are a number of conventional methods to support the head and protect the eyes and face of a patient from compression injuries during surgery which require the patient to be placed in a prone, face down, position for the long periods of time involved in surgery. One method conventionally used is placement of the patient's head and face in a horseshoe shaped frame supporting a foam pillow which holds the patients face off of the operating table in a supported manner. The patient's eyes are generally taped shut when such a structure is used to keep them from contact with the foam and to prevent eye fluid drainage. This frame and pillow support however has inherent hazards of its own in that it cannot distribute pressure maximally over the surface of the head. Further, great care must be taken by the anesthesiologist and staff to make sure that any anesthetic equipment, such as endotracheal tubes, esophageal stethoscopes, or electronic sensing devices, are not dislodged or disrupted by gravity or patient positioning during the term of the surgical procedure. Such disruption or dislodgement of surgical equipment can cut off the air supply to the patient or lead to inaccurate readings by monitoring equipment.

Another method is simply to place the patient's face sideways on a pillow or towel located upon the surgical table. However, this method suffers from the danger of tubing collapse due to the patient's head weight, and even a face or

1 eye supported by a foam pillow may be damaged if the pressure
is uneven and remains on one area too long. Further, the
placement of the patient's face on a towel requires the head
to be turned one way or the other, placing pressure on one
side of the face which, as noted earlier, subjects the patient
6 to the potential of injury. Additionally, blood flow through
the veins and arteries of the neck may be impaired by this
twisted fashion of head support. Hazards to the patient
increase if the surgery requires a face down posture because
the danger of tube collapse from pressure or bending increases
11 with the tubes entering the patient's body through the mouth
or nose being compressed between the patient's face and the
operating table. With the entry points to the head out of
view, such constrictions of the tubes also remain out of
sight.

16 A further challenge facing surgical teams during surgery
on anesthetized patients is the seemingly simple task of
rolling the patient over from a supine position to a prone
position on the operating table or from a cart onto the
operating table. Generally, the patient at this point in the
21 surgical procedure is already intubated, asleep, and basically
"dead weight." In this physical state, the patient is at
great risk of injury during the roll over procedure,
especially to the neck area. Additionally vexing to the
surgical staff is the fact that the patient, with tubes
26 exiting the mouth and/or nose, must be rolled over, without

1 disturbing the tubes and without injuring the neck.

Concurrently during the roll over procedure, the surgical staff must plan ahead so that when the patient is placed face down on an operating table, the face is properly aligned with, and inserted upon or into the pillow, already located upon the table. This insertion of the face into the pillow is

6 conventionally done without the benefit of a pre surgery fit to make sure the face and pillow and frame mate in a manner that will accommodate the patient for the term of the surgery and protect the face from compression injury. Heads and faces being quite different amongst people in general, an optimum fit between face and pillow is achieved only a small percentage of the time. Once in this prone position, the danger of injury remains constant and continued and consistent vigilance by the surgical staff is required to ascertain, that in fact, the patient's airways are open, the eyes are not compressed, and the face is not being subjected to pressure at any point for a duration sufficient to cause nerve damage.

Finally, when the operation is over, the patient must again be moved off of the operating table and is generally rolled over onto a gurney in a reverse roll over procedure. Still anesthetized, the patient is at great risk of injury to the neck if the head is not adequately supported and manipulated during this roll over process.

Still further, if an emergency develops while the patient is in the face down prone position, requiring the patient to

1 be rolled to the supine position, valuable life saving time
can be lost trying to upright the patient without injury to
the neck, and without crimping the airway supply tubing and
monitoring equipment communicating through the nose and mouth
of the patient.

6 Further, patient size is also a factor in the fitting of
facial and head support. A child may have a very small face
and head and an adult a large one. Conversely, a large child
may have a head and face requiring support in areas much
different from a small stature adult.

14 U.S. Patent 5,220,699 (Farris) teaches an inflatable
pillow mounted inside a mask for variable support of differing
sized patients. However Farris requires the use of an
inflatable chamber which as taught is inflated once the
patient has already been rolled to the prone position. It
16 requires an air inflation device to function and lacks the
ability for an easy installation prior to surgery and will not
function without compressed air.

U.S. Patent 4,400,820 (O'Dell) teaches an apparatus using
pads and having a "T" shaped void which may be used in
21 combination with a support structure to hold the patient's
head. However, O'Dell does not allow for pre-fitting and pre-
installing the protective device prior to surgery and does not
aid in protecting the patient during roll over on and off the
table.

26

1 U.S. Patent 5,214,815 (Agbodoe) teaches a surgical
headrest with a removable foam pad; however, Agbodoe does not
provide any manner to pre-fit and install the device on the
patient prior to being asleep and it mounts to the table and
is intended for use after roll over thereon.

6 U.S. Patent 4,757,983 (Ray) features a pair of cushions
attached to a horseshoe-shaped frame for surgical head
support. However Ray also suffers from an inability to pre-fit
and install the device on patients prior to surgery while they
are awake as well as lacking any protective ability during
14 dangerous roll over onto the table and like the aforementioned
prior art, lacks the ability to see the patient's eyes and
face from the side or from above.

As such, there exists a need for a support device that is
easily modified to fit a variety of patients of differing
16 size, and that may be pre-fit to the patient prior to surgery
while the patient is alert and able to ascertain the comfort
or discomfort level of the device. Further such a device
should provide an additional manner to support the head and
maximally diffuse pressure over a large area while helping
21 prevent patient thermal heat loss during surgery, as well as
during the hazardous movement of the patient prior to and
after surgery. Such a device should also provide for easy
viewing of the patient's eyes and nose from a side and top
view during the operative procedure so that the patient may be
26 continually monitored by the staff.

1 A further need exists for such a device that may be
cooperatively engaged with a positionable mount or used by
itself if needed yet still provide a view of the eyes and
ocular area of the patient from looking inward from the side.

6 **SUMMARY OF THE INVENTION**

The present invention relates to a new and improved
protective helmet apparatus which provided functionally
through the ability to vary the configuration for the physical
characteristics of patients undergoing general anesthesia
11 during surgery, and provide optimum cranial support to the
12 patent using differing configurations of the various parts of
the device. Concurrently, the device, when using a
substantially transparent helmet casing and operatively placed
apertures provides the medical professionals operating on the
16 patient, easy viewing of the patients facial features and easy
access to the nasal and oral passages of the patient in either
the prone or supine position. The device is best made of
modular construction allowing for the substantially
transparent helmet casing to fit a variety of different sized
21 patients. Interchangeable and replaceable cushions of
variable dimensions on one surface to accommodate different
patient facial structures are positionaable in a plurality of
interchangeable light weight helmet casings. The cushions on
their exterior surface are dimensioned for a registered fit
26 with the helmet casing surface and apertures in the cushion

1 register with apertures in the helmet casing. The cushions
can also be color coded to designate different sizes to
accommodate different sized patients. If desired, while not
the best mode for maximum support and positioning, the
cushions themselves can be used without the helmet casing, yet
6 still provide a side view of the patient's eyes and temple
area during the procedure through an aperture communicating
through a sidewall to the face of the patient. Such might be
the case in emergencies when sufficient helmet casings are not
available or when a low mount of the patient's head is
11 desirable.

The device is especially useful in that it allows for
pre-fitting of the patient while the patient is awake and
alert using modular pads of differing facial dimensions and
having a rear or mask side dimension configured to fit into a
16 registered position in the helmet casing. While the current
best mode combines the proper sized cushion with the
appropriate helmet casing for a mount on the table surface,
even using the facial cushion by itself, if desired, yields a
substantial increase in utility over prior art due to the
21 viewing of the patient's eyes and temple area from the side
afforded by the apertures therefor. The device having the
pre-fitted cushions or pads mounted into the helmet casing,
and featuring appropriate indentations on the facial contact
surface, evenly diffuses pressures on the face of the wearer
26 and may be worn into surgery such that the surgical team need

1 not worry about trying to fit the patient with pillows or pads
in a table mounted frames after the patient is asleep.

For use in a variety of patients in prone or supine
positions during surgery the various embodiments of the device
offer a plurality of ways in which to support the patient's
6 head. One embodiment features a hinged or optionally
removable lower chin support which is moveable from a first
position in operable contact with the helmet casing to a
second position out of such contact, thus allowing the
surgical team easy access to the entire face and mouth area
14 for insertion of required tubing into the patients mouth
and/or nose. The chin support is thereafter reinstalled to
provide lower chin support with the entire helmet being worn
by the patient for the rollover procedure on and off the table
to protect the patient from injury during the course of the
16 surgical procedure. Or, the chin support may be provided by
the cushion itself with the cushion and the helmet casing
extending below the mouth area of the patient thus eliminating
the detachable chin support.

As the device may be pre-fitted for optimal weight
21 diffusion and comfort and can be worn during the movement of
the patient on and off the operating table, the surgical team
is relieved on concerns of whether the device to hold the face
and head actually fits the patient. Further, an optional
rotating handle upon the top of the helmet provides a handy
26 gripping point for the head for the surgical team to help

1 prevent neck injury during roll over of the patient on and off
the table. By placement of a hand on the face of the mask and
another on the rotating handle, smooth and continual support
may be provided to the neck and head area when the patient is
being rolled over on or off of the operating table.

6 Another embodiment of the device features a helmet
casing, which is best made of substantially transparent
material, having an interior cavity that is formed to register
with a cooperatively engageable cushion. The cushion is made
from foam or other soft resilient material and is dimensioned
14 on one surface to accommodate the patient's face, and on the
other opposite or exterior surface, to register with the
interior cavity of the helmet casing. A raised border about
the exterior surface perimeter of the cushion could be formed
during manufacture to provide an additional means to register
16 and align the cushion with the openings in the helmet casing.
Optionally, the cushions may be color coded for patient facial
sizing. One or a plurality of apertures communicating through
the helmet casing register with appropriately configured
apertures communicating between the two surfaces of the
21 cushion and provide an in line cavity from the patient's face
through the casing. This in-line cavity provides access to
the patient's mouth, nose, and eyes. By dimensioning the
cavity to extend around the patients face at eye level, easy
viewing of the patient's eyes and nose is provided to the
26 operating room staff.

1 An additional embodiment of the device would feature a
plurality of legs on the exterior surface of the helmet casing
to provide a raised mount above the operating table. The legs
can be adjustable for height above the operating table to
provide comfortable posture to the patient while affording the
6 best access and view of the face of the patient to the staff
of the operating room.

In the current best mode, an optional base may also be
provided which provides a releasable but solid mount for the
helmet casing using cooperating fasteners located on the mount
and the exterior of the helmet casing. The mount acts as a
positioner by providing a stable mount for the helmet casing
and optionally may provide additional utility in the best mode
with a surface mounted mirror for providing a reflective view
of the patient's eyes and nose to the staff of the operating
room while the patient is face down and the staff is
substantially in an upright position. This eliminates the
constant need for members of the operating team to bend over
to inspect the face and eyes of the patient during surgery in
providing a continuous view of the eyes and face of the face-
21 down patient. Additional utility is provided by an optional
light means positioned on the upper surface of the mount
adjacent to the mirror by illuminating the patient's face
through the in-line cavity and enlightening the reflection on
the mirror for the staff to more easily view it from a
26 distance.

1 An object of this invention is to provide a helmet which prevents injury due to ocular compression during surgery by minimizing ischemic damages through maximal diffusion of pressure about the patient's head.

6 Another object of this invention is the provision of a protective device for use during surgery which allows for pre-fit of the patient prior to surgery while the patient may comment on the comfort or discomfort level of the device.

11 A further object of this invention is to provide a protective helmet for surgery which provides a facial and chin support to the patient which is easily removable by the surgical team for insertion of required devices into the mouth and nose of patient and thereafter easily reinstalled.

16 An additional object of this invention is the allowance of easy access to and viewing of, the patients eyes and temple area through apertures in the device positioned to accommodate such access and viewing.

21 Another object of this invention is the provision of a protective surgical helmet of modular construction which allows for positioning of different sized facial cushions and components into the helmet casing to accommodate the head different sized patients.

26 An additional object of this invention is providing an easily sterilized protective helmet through the use of easily sterilized cushions or inexpensive throw away insertable cushions removably mountable inside an easily sterilized or

1 cleaned helmet shell.

A still further object of this invention is to concurrently provide easy viewing of the eyes and mouth area of the patient while the device is mounted upon the patient.

A still further object of the invention is the provision
6 of the ability to control and alter the temperature of the device to aid in temperature control of the patient during surgery.

An additional object of this invention is to provide easy viewing of the patients facial features to the operating staff
14 using while concurrently allows the staff members to remain substantially upright through the provision of a reflective means of the face of the patient.

Further objects of the invention will be brought out in the following part of the specification, wherein detailed
16 description is for the purpose of fully disclosing the invention without placing limitations thereon.

BRIEF DESCRIPTION OF DRAWING FIGURES

Figure 1 is a perspective frontal view of the protective
21 helmet device showing the chin support in a mounted position.

Figure 2 is a frontal view of the device featuring the hinged repositionable chin support.

Figure 3 is a rear exploded view of the protective helmet device showing the modular pads for the ocular area and chin
26 support.

1 Figure 4 shows the helmet with detachable and
repositionable chin support portion.

Figure 5 depicts the helmet with detachable and
repositionable chin support slidably mountable to the helmet.

Figure 6 depicts a side view of the apparatus showing the
6 optional handle side grip and the flat face for secure
positioning on the surgery table.

Figure 7 depicts another embodiment of the device
featuring an exploded view a helmet casing of unitary
construction with insertable modular pad providing facial and
chin support in a single combined unit.

Figure 8 depicts the helmet casing of figure 7 in a
registered position removably or otherwise attached to a mount
with optionally mirrored surface for reflection of the
patient's face therein.

Figure 9 is a top perspective view of the facial cushion
showing the facial indentation and apertures therethrough.

Figure 10 depicts ^{an} end cut away view of the facial
cushion for removable mounting to the helmet casing showing
the facial indentation formed to accommodate patient facial
21 structures therein, and the lip for registration with the
casing edge.

Figure 11 depicts a bottom perspective view of the helmet
casing showing the unitary construction and the legs affixed
to the exterior which provide an elevated mount along with the
26 communicating aperture through the casing.

1 Figure 12 depicts a top view of the mounting base for the helmet casing with a surface mounted mirror and light source.

Figure 13 depicts a side view of the mounting plate with a mirror and cooperatively engageable mounts on the upper surface.

6 Figure 14 is a top view of the upper surface of the mounting plate showing the mirror and mounts.

Figure 15 is a ~~top~~ view of the removably attachable heating blanket with temperature control and clip.

DETAILED DESCRIPTION OF THE PREFERRED

EMBODIMENTS OF THE INVENTION

Referring now to the drawings, Figure 1 depicts a preferred embodiment of the modularly assembled protective surgical helmet apparatus **10** featuring the helmet casing **12** which is best made from a substantially rigid but easily molded material such as plastic. The plastic casing should also be resistant to the heat or chemicals sufficient to allow for sterilization between uses. The modular version of the helmet casing **12** mates with a chin support **14** using conventional registering mating positioners such as registration pins **16** which correspond to apertures **18** upon the helmet casing **12**. Of course the registration pins **16** and apertures **18** might be reversed in positioning or other conventional means of registration and dismountable attachment may be used to achieve a properly aligned mounting of the chin

1 support **14** to the helmet casing **12**. Alternatively, the chin
support **14** can be slidably mounted to the helmet casing **12**
using a cooperating pair of slide mounts **53** and **51** depicted in
figure 5 wherein the chin support **14** with one half of the
fastener slid mount **53** would be lined up with the helmet
6 casing **12** and cooperating slide mounts **51** and **53** and thereupon
the chin support **14** would slide onto the helmet casing **12** by
pushing it into position and interfacing the cooperating slide
mounts **51** and **53**. Cooperating fasteners **20** and **22** in the two-
piece embodiment, such as hook and loop fabric, are used to
11 maintain the chin support **14** in operative contact in a first
position wherein it is in a removably fixed position upon the
helmet casing **12**, however, other conventional mating fasteners
such as plastic or metal releasable locking fasteners can also
be used and are anticipated. Cooperating fasteners **20** and **22**
16 would also be used to maintain the hinged chin support **14** and
slidable chin support **14** in the first position of operable and
registered contact with the helmet casing **12** although in the
case of the slidable version friction alone in the cooperating
slides may be sufficient to releasably hold the chin support
21 **14** in proper contact with the helmet casing **12**.

The dismountable chin support **14** may also be attached to
the helmet casing **12** at one end using a conventional metal or
plastic hinge fastener **34** such that the chin support **14** will
swing away from its first position in operative contact in a

1 registered mounting with the helmet casing **12**. This
embodiment allows for easy access to the patient's facial area
during surgery or emergencies while maintaining the chin
support attached to the helmet casing **12** when swung to the
second position out of operative contact with the helmet
6 casing so as to avoid loss of the chin support **14**.

Straps **24** having cooperating fasteners **25** at their distal
ends securable to mating cooperating fasteners **25a** upon the
helmet casing **12** may be optionally used to secure the helmet
casing **12** upon the face of the patient once the properly sized
ocular cushion **26** has been removably mounted into the helmet
casing **12**.

In certain instances the helmet casing and chin support
might also be formed as one piece for surgeries where a
removal of the chin support **14** is not a major consideration
and for ease of use and reduction in parts to inventory. In
such a one piece embodiment the support to the face of the
patient provided by the ocular cushion **26** and chin cushion **28**
would be provided by a single once piece facial cushion **31**
which is configured to removably mount into a one piece

21 embodiment of the helmet casing **12** in a registered position,
therein thereby providing stable even support the entire face
of the patient from forehead to chin. In the one piece
version of the helmet casing **12** the front surface would be
extended to a point below the chin and thereby accommodate a

1 once piece facial cushion **31** and apply complete support to the head of a patient.

The ocular cushion **26** and chin cushion **28**, or one piece facial cushion **31**, if reusable, are best made of a closed cell foam material or other cushioning material which does not

6 absorb fluid easily to allow the cushions to be sterilized in the conventional fashion for reuse. In many instances sterilization may not be necessary and a simple washing may provide the required level of cleanliness. In such cases the material used will be durable for reuse and resistant to

11 cleaning to allow multiple uses of the cushions **26**, **28**, or **31**.

However, for ease of use and to maintain a highly sterile field about the patient, disposable ocular cushions **26**, chin cushions **28**, and one piece facial cushions **31** may be more desirable since they could be used once and replaced after
16 each operation to maintain a highly sterile or sufficiently clean field. The best mode as to disposable or reusable is best determined by the criteria of the hospital or surgery center involved and their individual criteria.

Optionally, for an even more custom fit to individual
21 patients is desirable, the ocular cushion **26** and chin cushion **28** or the once piece facial cushion **31** may also be made inflatable with gas or fluid or silicone or other gel such that they may be adjusted in size and flexibility by filling them with a gas or liquid into the cushions through a sealable
26 orifice communicating through the wall of the cushion.

1 The ocular cushion **26** may be made in a set of multiple
ocular cushions **26** varied in dimensions of both thickness and
width and have variable sized and located ocular apertures **27**
therein to best accommodate the size and facial structure of a
variety of differing sized individuals using the same helmet
6 casing **12**. The chin cushions **28** may also be from a set of such
chin cushions **28** varied in dimensions of both thickness and
width to achieve optimum fit on individual patients. The one
piece facial cushion **31** used with the one piece embodiment of
the helmet casing **12** provides the same adjustable utility and
11 can be varied in the same fashion by providing multiple facial
cushions **31** for use as a kit to be combined with one piece
helmet casing **12**. The facial cushion **31** has a facial
indentation **35** ^{not on 31} formed on a first side of the facial cushion **31**
sized to accommodate the face size of the intended patient.
16 The opposite side or exterior surface **38** ^{NS} of the facial cushion
31 would be dimensioned for cooperative engagement with the
interior surface **35** of the one piece embodiment of the casing
12. By varying the dimensions of the cushions **26** and **28** or
31, and the size and location of the apertures therein, and
21 matching them to the properly sized one or two piece helmet
casing **12**, virtually any adult or child may be fitted to wear
the resulting assembled device **10** comfortably with optimal
support of the facial structure of the cranium and maximal
diffusion of pressure and weight about the face and sides of

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1 When using a disposable form of cushions **26** and **28**, and **31**
adhesive or other means for a removable attachment can be
placed upon the helmet side of the respective cushion surface
for an easy mount of the cushions into the helmet casing **12**
and/or repositionable chin support **14**. Such a disposable form
6 of cushions **26**, **28**, and **31**, would be kept sterile inside a
sealed wrapper in the conventional manner and removed and
mounted to the inside face or interior surfaces **35** and **36** of
the helmet casing **12** and chin support **14** respectively as
necessary in the configuration decided upon, using
11 conventional peel and stick adhesive pads positioned upon the
surface of the cushions to attach them to the helmet interior
surface **35**.

The device **10** offers great utility to the user since it
is capable of using either disposable or reusable cushions for
16 cushions **26**, **28**, or **31**, or combinations thereof at the
discretion of the professional using the device. Where
disposable cushions are desirable due to their ease of use and
lack of the need for sterilization, just the helmet casing **12**
and chin support **14**, if used, need be sterilized. Or, in the
21 case of the once piece casing just the casing need be
sterilized if required. However, a reusable form of cushions
26, **28** and **31** may also be used in the device **10** where the
cushions can be sterilized between use, or, in instances where
sterilization is determined not to be needed they need only be

1 washed. Or, a combination of reusable and disposable cushions
26, 28 and 31 may be used should such be desired or required
if a reusable cushion is lost or damaged.

In use, with the two-piece embodiment, the patient would
be measured for the optimum helmet casing 12 size which would
6 be chosen from a plurality of available interchangeable helmet
casings available, and, a chin support 14 of proper size which
would be chosen from a plurality of interchangeable chin
supports capable of attachment to said casing 12. Also chosen
to accommodate differing facial and head dimensions would be
11 the properly dimensioned cushions 26 and 28, from a set of
interchangeable cushions, to allow the patient maximum comfort
and diffusion of pressure about the surface of the face and
side of the head. The patient could be given samples of the
different sizes of cushions 26 and 28 from a set of variable
16 dimensioned cushions 26 and 28 to which the patient would give
input as to the best possible fit or a medical technician
might also help determine the optimum casing and cushion
dimensions with or without the patient's input. This
availability of an assortment of cushions and assembled helmet
21 sizes allows for a modular system of helmet casings 12 and
attachable chin supports 14 assembled to the helmet, to be
used in conjunction with the desired dimension of cushions 26
and 28, also from a set of such cushions of differing
dimensions, to achieve the optimum fit on a variety of sizes

1 of patient heads.

Once the optimum dimensions of the cushions **26** and **28** are determined, yielding a comfortable fit and maximal pressure distribution about the face and sides of the head, the cushions **26** and **28** are removably mounted into the interior of both the helmet casing **12** and chin support **14** using the aforementioned adhesive or fastener cooperating mounts **32** located upon the cushions which attach to cooperating mounts **33** which are positioned upon the helmet casing **12** and chin support **14** respectively. This is accomplished in a manner to allow for the mounting the cushions **26** and **28** into the cooperatively configured interior surfaces **35** and **36** of the helmet casing **12** and chin support **14** respectively.

The inside surface **35** of the helmet casing **12** features a casing ocular aperture **37** and the chin support **14** has a chin support aperture **39**. When properly positioned in the cooperating inside faces of the helmet casing **12**, the aperture **27** in the ocular cushion **26** will be relatively in line with the casing ocular aperture **37** such that the eyes and nose and some surrounding portions of the patient's face, or the ocular area of a patient's face, may be easily viewed through the ocular aperture **37** when the device **10** is being used during surgery after being positioned upon the patient's face. The ocular aperture **27** might best be made slightly larger than the casing ocular aperture **37** to allow for easy mounting of the

1 ocular cushion **26** into the helmet casing **12** to allow for the
patient's eyes and surrounding skin area to be viewed through
the casing ocular aperture **37** and relatively in-line cushion
ocular aperture **27**. Where the casing ocular aperture **37** wraps
around to the side of the helmet casing **12**, the in-line ocular
6 cushion aperture **27** would also wrap around in a relatively in-
line position with the casing ocular aperture **37**. This in
line relationship of apertures creates a viewing passage
communicating through the helmet casing **12** and apertures **37**
and **27** thus revealing the patient's temple area of the head in
11 addition to the ocular area of the face and the nose. This in
line relationship of the apertures of the cushions **26** and **28**
with the casing apertures **37** and **29** also allow for the passage
of conventionally used tubes through the in line apertures
into the patient's nose and/or mouth for providing life
16 support during the operation. Further, the cavity formed by
the in line cushions **26** and **28** attached to the helmet casing
12 and chin support **14** gives protection to these tubes at the
critical entry and exit positions on the patient at the nose
and mouth such that the tubes, inside the cavity, will not
21 bend to a point where flow therethrough is interrupted with
possible life threatening consequences to the patient. For
additional utility, optional tube passages **44** communicating a
tubular passageway from the interior of the device **10** to the
exterior, can provide for communication of tubes or sensing

1 device wires therethrough to the patient. Exterior mounted
optional tube positioners **46**, of hook and loop fabric or other
type of fastener suited to the job, can be optionally mounted
upon the exterior of the device **10** to hold tubing and/or wires
for monitoring the patient operatively therein during surgery.

6 Snap on fasteners may also be optionally attached at the
exterior of the device **10** to hold tubing and the like. By
providing optional strategically placed snap mounts **48** the
snap on fasteners may be placed in differing positions about
the exterior to hold the tubing and/or wiring required for
certain surgical procedures in place and out of harms way.

11 The chin support aperture ^{NS}~~39~~ of the two-piece embodiment
lines up with the bottom of the casing ocular aperture **37** when
the dismountable chin support **14** is operably mounted to the
helmet casing **12**. The chin support aperture **39** allows for
16 viewing and access to the lower mouth area of the face of the
patient with the chin of the patient being supported by the
chin aperture ³⁹~~29~~ in chin cushion **28** removably attached to the
interior surface **36** of the chin support **14**.

Added utility is provided by the device **10** operably
21 mounted to the face of the patient using attributes of the
frontal surface **41** of the device **10**. This frontal surface **41**
if made flat like that of the upper table surface **64** of a
conventional operating table, allows for a stable support of
the patients face inside the properly mounted device **10** when

1 the frontal surface **41** is placed upon the operating table
without a mount if such a positioning is desired. For
especially stable maintenance of the patient's head when in a
sideways position a second side flat surface area on the
sidewall **47** area may be located on one or both sidewalls **47** of
6 the device **10**.

Or, as depicted as the one-piece embodiment of the device
in figure 7, legs **60** attached to the casing exterior surface
49 can provide both a means for elevation of the helmet casing
12 above the couplings **62** on the mounting plate **66** and
11 underlying table surface **64** and if desired, registration using
at least two of the couplings **62**. The couplings **62** as
depicted, are dimensioned to cooperatively engage the distal
ends of the legs **60** and can be mounted directly to the
operating table surface **64** using a means for attachment to the
16 operating table surface **64** such as adhesive **65**, frictional
engagement, or other means of attachment to the table surface
64. Or in the current best mode a mounting plate **66** would
have the couplings **62** mounted thereon positioned to provide a
registerable mount through cooperative engagement with an
21 axial leg aperture **63** in the distal end of the legs **60**.

Insertable leg extensions **61**, made of differing lengths to
achieve the desired elevation, provide an adjustable means for
elevation would fit between the leg apertures **63** and onto the
couplings **62** providing a means for height adjustment of the

1 helmet casing **12** above the underlying table surface **64** to
accommodate various posture positions for the patient's head
and neck.

The single piece embodiment of the helmet casing **12**
features a front wall surface **41** which extends laterally and
6 then curves to a pair of side walls **47** both of which begin at
one side with their communication with the front wall surface
41 and extend vertically at an acute angle from the front wall
surface **41** to form the two substantially parallel sidewalls
47. In this embodiment the casing ocular aperture **37** in the
current best mode, is enlarged and extended around and through
the front wall surface **41** and upward onto and through at least
one side surface **47** of the helmet casing **12** providing a clear
view of the patients eye, and face in the temple area, as well
as the area in front of the nose, from one or both sides of
16 the device **10**. Extending the casing ocular aperture **37** and
the cushion ocular aperture **27** up at least one sidewall **47**,
whether they are used in combination or when the cushion might
be used by itself, thus provides a means to view the eye
socket and surrounding area through the sidewalls **47** of the
21 device of the patients who might use the device. In the
current best mode, the ocular apertures of both the once piece
helmet casing **12** and the facial cushion **31** extend up both
sidewalls **47** to provide a viewing passage **82** of both eyes and
the surrounding temple area of the head of the patient through

1 the sidewalls **47**. Viewing of the temple area is also achieved
through the transparent material making up the helmet casing
12 and would allow for a larger ocular cushion aperture **27** to
provide more of a view of this area thus allowing even greater
viewing of the patients eye area much like a window.

6 During times of moving of the patient for roll over or
off of the surgical table and onto a gurney, an optional top
handle **40** attached to the top area of the helmet casing **12**
portion of the assembled device **10** allows medical personnel a
solid gripping point for providing head and neck support to the
11 patient while being rolled over or otherwise moved. By
holding the patient's neck with one hand and the handle **40** in
the other, essential support can be provided to avoid injury
to the anesthetized patient. A roller or ball or other
conventional bearing **42** can also be placed at the base of the
16 handle **40** should easy rotation of the handle **40** be desired
during use. Such a rotation of the handle **40** on the bearing
42 allows for a smooth roll over of the patient with the
patient's neck concurrently supported, thus minimizing
possible neck injuries during roll over and other hazardous
21 patient relocation procedures.

Additional utility in the disclosed apparatus herein is
provided by the insulating factor provided to the patient
wearing the surgical helmet **10** and cushions **26**, **28**, and **31**,
when mounted upon the face of the patient during a surgical
26 procedure. Operating rooms are conventionally kept quite cold

1 to keep medical personnel and surgeons cool and alert during
surgical procedures. The patient however is generally
unclothed during such procedures and can suffer discomfort
from the overly cool environment of the room. The cushions
26, 28 and **31**, form to the face of the patient and are mounted
6 upon the interior surface **35** of the device **10**, and thereby
encompass the face and part of the sides and top of the head
of the patient. The result being that the face, sides, and top
of the patient's head are insulated from the cool room
temperature, helping to keep the patient warmer in the
unnaturally cool environment of the operating room.

Further utility is also provided by this surgical helmet
device **10** through the use of optional slot passages **45** located
in the face of the device for positioning of tubes therein.
During a surgery requiring the patient to lay face down, tubes
16 providing breathing supplies to the patient may be positioned
in a slot configured to allow the tube to recess therein such
that the tube will not collapse when the patient is face down
and the tube is between the table and casing exterior surface
49 of the device **10**. Such a slot passage or multiple slot
21 passages **45** may be positioned about the face of the helmet in
other locations than shown.

Figure 7 depicts a preferred embodiment of the device **10**
featuring an exploded view showing the helmet casing **12** of a
one piece or unitary construction. In this embodiment, the
26 casing walls are best constructed of rigid substantially

1 transparent material such as plastic in a unitary
construction. This embodiment provides the same desired
support for the chin and face provided by the two-piece
embodiment accomplishing this support with a cooperatively
engageable one piece facial cushion **31**. This one piece
6 embodiment continues to provide proper chin and face support
by slightly elongating the helmet casing **12** in a one piece
design and combining the ocular cushion **26** and chin cushion **28**
into a one piece facial cushion **31** which is dimensioned on the
exterior surface **70** of the facial cushion **31** for cooperative
11 engagement with the interior surface **35** of the helmet casing
12. The facial cushion **31** is dimensioned on the interior
surface **69** to provide a comfortable fit to the face of the
patient for which it is to be used. In use, in essentially
the same manner as the two-piece embodiment, the intended
16 patient would be measured for the optimum facial cushion size
31 which would be chosen from a plurality of available
interchangeable facial cushions **31** available for registered
cooperative engagement with the one piece helmet casing **12**.

In many cases only one or two different sized helmet
21 casings **12** would be needed in inventory to be mated with
cushions to accommodate a very large number of differently
dimensioned facial cushions **31** since the size, thickness, and
exterior and interior dimensions of the facial cushion **31** may
be varied to accommodate the different facial dimensions of..

1 different patients. This is accomplished by the variance of
the dimensions of the indentations **68** formed on the interior
surface **69** of the facial cushion **31** which are used accommodate
the facial dimensions of the intended patient. The exterior
surface **70** of the facial cushion **31** would be dimensioned for
6 operative cooperative engagement with the shape and dimensions
of the interior surface **35** of the helmet casing **12** in the
aforementioned registered and cooperative engagement therein.

The registration and cooperative operative engagement
between the cushion **31** and helmet casing **12** would be
11 maintained using a means for registered engagement of the
facial cushion **31** with the helmet casing **12** which includes
one, or a combination, of registration means, from a group of
such registration means consisting of frictional engagement
between the interior surface **35** of the helmet casing **12** and
16 exterior surface **70** of the facial cushion **31**, adhesive **65**, a
lip **71** located about the upper exterior surface **70** of the
facial cushion **31** in a position to cooperatively engage the
upper edge **75** of the sidewalls **47** of the helmet casing **12**, or,
registration pins **73** attached to the body of the facial
21 cushion **31** in positions to cooperatively engage registration
apertures in the casing, in this case axial passages **77** formed
into the legs **60** and sized to accept the registration pins **73**
in a removable cooperative engagement. Since the registration
pins **73** would in the current best mode be molded of the same

1 flexible foam as the facial cushion **31** they offer the current
best mode of registration since the registration pins **73** will
compress during insertion into the axial passages **77** and then
naturally bias against such compression into removable biased
frictional engagement with the interior of the axial passages
6 **77**. While the aforementioned are the current best mode of a
registration means between the facial cushion **31** and the
helmet casing **12**, those skilled in the art may devise other
such means of registered engagement and such are anticipated.

In fitting the patient for maximum comfort and support,
11 the patient could be given samples of the differently
dimensioned facial cushions **31** from an available plurality or
set of variably dimensioned facial cushions **31** to which the
patient would give input as to which formed indentations **68**
provide the best possible fit to the facial dimension of the
16 patient. Or, a medical technician might also help determine
the optimum helmet casing **12** and facial cushion **31** dimensions
with or without the patient's input. This availability of an
assortment of differently dimensioned facial cushions **31** to
cooperatively and operatively engage one or a plurality of
21 helmet casings **12**, allows for a kit or modular system of
helmet casings **12** and attachable to facial cushions **31** to
achieve the optimum fit on a variety of sizes of patient
heads. For easy identification of size the facial cushions **31**
would be marked with appropriate indicia **30** in writing showing

1 a size designation or in the best current mode with indica in
the form of color coding for easy identification. The color
coding or written indica **30** to identify size could be imparted
by extruding it in the color of the foam making up the facial
cushion **31** or silkscreened or otherwise applied on the surface
6 of the cushions **26, 28, and 31.** Once the optimum dimensions
of the facial cushion **31** are determined, yielding a
comfortable fit and maximal pressure distribution about the
face and sides of the patient's head, the facial cushion **31** is
removably mounted to the interior of the helmet casing **12**
14 using the aforementioned means for registered engagement of
the facial cushion **31** with the helmet casing **12.**

16 The one piece facial cushion **31** offers an additional
benefit in that in some cases it might be used without the
helmet casing **12.** Use without the casing might occur when an
especially low mount of the patient's head is desired for
posture or for the surgical procedure, or, in an emergency or
other situation where the additional support and utility of
the in-line helmet casing **12** is not required. Use of the
facial cushion **31** by itself, while not offering the full
21 utility of the best mode in combination with the helmet casing
12, does provide the easy side viewing of the patients eyes
through the elongated ocular cushion aperture **27** and still
provides improved support and padding to the patient's head
during surgery. Consequently, it is anticipated that the

1 cushion might be used alone without the casing **12**, and while
not providing all of the utility of the device featuring the
combination of the facial cushion **31** with the helmet casing
12, using the cushion alone would still provide much better
support to the patient's face, a clear view of the eyes
6 through the elongated cushion ocular aperture **27** and a solid
support to the patient's head on the table through frictional
engagement therewith.

Or, in some cases, where reuse of the cushion may not be
advisable due to the patient, the helmet casing **12** might also
11 be formed into the exterior of the facial cushion **31** itself.
This could be done if a substantially rigid shell **80** were
formed about the exterior surface **70** of the facial cushion **31**
by either lamination thereto or in the molding process and
would provide rigid support to the facial cushion **31**. However
16 this configuration with the helmet casing **12** as attached to
the facial cushion **31** as a laminated or permanent shell yields
less utility in that different facial cushions **31** for
different sized patients could not be matched to a single
helmet casing **12** thus requiring more stock of product. But,
21 differing user criteria and requirements may call for the
facial cushion **31** to be thus used and manufactured with a
casing formed by the rigid shell **80** formed on the outside
surface for use without the additional advantages afforded by
mating with the helmet casing **12** and such is anticipated.

1 While the current best mode of the device, affording the most
utility, is the registered engagement of a properly sized
facial cushion **31** with the helmet casing **12**, the cushion-only
embodiments offer the operating staff the option to use the
facial cushion **31** without the helmet casing **12** and still
6 achieve much better support of the patient's head, thermal
insulation and view of the patient's eye and surrounding
temple area **74** which is a marked improvement to the current
practice of placing the head on a towel. The very nature of
the exterior surface **70** of the soft foam facial cushion **31**
11 would provide a good frictional mount to the surface of the
table surface **64** and good side and frontal support to the head
of the patient with a concurrent view through the elongated
casing ocular aperture **37** reaching around the side to allow a
view of the patient's eye socket from an operative distance.
16 Use of the facial cushion **31** could also occur if there were a
shortage of helmet casings **12** for the number of patients
requiring surgery during an emergency situation. Consequently
it is anticipated that the facial cushion **31** could be used by
itself in certain instances and would still be a substantial
21 improvement for a mount and support of the patient's head than
the present art.

To provide an excellent view of the patient's facial
features, as with the two piece embodiment, the interior
surface **35** of helmet casing **12** features a casing ocular
26 aperture **37** communicating through the casing front wall **41**

1 surface and side walls **47** and the chin support aperture **39**
formed into the front wall **41** surface and communicating
therethrough. The one piece embodiment the helmet casing **12** as
noted also features an elongated casing ocular aperture **37**
which wraps around the helmet casing **12** to determined
6 termination points in one or both substantially parallel side
walls **47**, and thus allow for easy viewing of the eye area of
the patient during use by looking through the in line casing
ocular aperture **37** and cushion ocular aperture **27**. In the one
piece embodiment this casing ocular aperture ³⁷ communicates
11 with the chin support aperture ²⁹ ~~38~~ to yield a somewhat figure
eight shaped aperture when the casing is viewed from the
bottom. The in line ocular cushion ocular aperture **27** where
it intersects the cushion chin support aperture **39**, yield a
^{nose} nasal cavity **57** the area of which is defined by the thickness
16 of the wall surface of the facial cushion **31** and the perimeter
of the intersecting chin support aperture **39** and the cushion
ocular aperture **27**. Along with providing a passageway for
tubes to the patient, the nose cavity **57** also yields a good
view of the nose and facial area around the nose when the
21 patent is in the prone position, providing additional utility
to the device.

When properly positioned, the cooperating engagement of
the facial cushion **31** and helmet casing **12**, will place the
cushion ocular aperture **27** substantially in line in a

1 registered position in relation to the casing ocular aperture
37. The ocular cushion ocular aperture 27 might best be made
slightly larger than the helmet casing ocular aperture 37. This
slight increase in size provides for easy mounting of the
facial cushion 31 into the helmet casing 12 to a position to
6 allow the patient's eyes and surrounding skin area to be viewed
through the wrap around casing ocular aperture 37 and
relatively in-line cushion ocular aperture 27. When the helmet
casing 12 is substantially transparent material, as in the
current best mode, the increased size of the apertures of the
11 facial cushion 31 also increase the area around the eyes and
nose of the patient that can easily be viewed since these areas
may be viewed through the helmet casing 12 itself.

As noted, in the current best mode, the casing ocular
aperture 37 wraps around from the front to both sides of the
16 helmet casing 12. The ocular cushion aperture 27 would also
wrap around substantially the same such that when mounted it
would engage the casing ocular aperture 37 in a relatively in-
line position, registered with the ocular casing aperture 37. A
viewing passage 82 provides a means to view the eyes and nose
21 and some surrounding portions of the patient's face through the
sidewall 47 is thus defined and provided by the in-line
relationship of the wrap around facial cushion ocular aperture
27 and the casing ocular aperture 37 and the cushion chin
support aperture 39 and the casing chin aperture 29 thus

1 forming the viewing passage communicating through the helmet
casing **12** and the apertures in the facial cushion **31** providing
an excellent view of the patient's temple area of the head in
addition to the ocular area of the face and a nose cavity **57**
for accommodating and viewing the nose from both sides of the
6 device and well as from below the device when mounted on the
operating table. This in-line relationship of the cushion
apertures **27** and **39** with the casing apertures **37** and **29** also
allows for the passage of conventionally used tubes through the
in line apertures into the patient's nose and/or mouth for
11 providing life support during the operation.

Figure 8 depicts the facial cushion **31** inserted and
registered in position with the helmet casing **12** which is in a
registered position removably attached to an optional mount
plate **66** using couplings **62** configured to cooperatively engage
16 the distal ends of the legs **60** which are attached to the helmet
casing **12** at their opposite ends. The couplings **62** are depicted
as pins that insert into indents in the legs **60** but this
arrangement could be reversed with the legs positionable into
indents in the mounting plate **66** or other means for attachment
21 of the legs **60** to the couplings **62** could be used and are
anticipated. If needed to adjust the height of the helmet
casing **12**, and thus the height of the head of the patient for
comfort or function, one or a plurality of leg extensions **61**
may be used to adjust the height as desired. The leg extensions

1 **61** would of course be configured to operatively engage in a fit
between the legs **60** and the couplings **62**.

 The couplings **62** alone using adhesive or other manner of
attachment could be pre-installed to the operating table
surface **64** in cases where the optional mounting plate **66** is not
6 desired, however in the current best mode, the mounting plate
66 positioned on the operating table surface **64** would provide
the couplings **62** attached in positions to cooperatively engage
the distal end of the legs **60** to thereby provide a stable means
of elevated attachment of the helmet casing **12** above the table
11 surface **64** in registered engagement with the mounting plate **66**.

 By the provision of a means for elevation, through the
provision of legs **60** to slightly elevate the helmet casing **12**
above the operating table surface **64**, and the means for
elevation adjustment using the leg extensions **61**, or other
16 manner of extending the length of the legs **60** such as
telescopic legs, or legs extending with pins to hold the
elongation of the legs, better patient posture is achieved by
keeping the patient's neck in line. Elevating the helmet
casing **12** and patient therein also elevates the casing ocular
21 aperture **37** and casing chin aperture **29** thereby allowing better
views therethrough of the patient for direct viewing by the
staff. The casing ocular aperture **37** being extended around the
frontal area and communicating between the casing interior
surface **35** and casing exterior surface **49** and extending to the

1 side area of the helmet casing **12**, provides an easy and clear
view of the patients eye and temple area **74**. For additional
utility, the aforementioned optional tube passages **44** could be
operatively positioned in the once piece embodiment of the
helmet casing **12** to provide a tubular passageway from the
6 interior of the device **10** to the exterior for the various
devices requiring such.

While elevating the helmet casing **12** provides extra room
between the table and the in-line apertures to allow better
viewing of the patient from the side and below, in the current
11 best mode, the placement of a mirrored surface **72** on the upper
surface **67** of the mounting plate **66** provides additional utility
through the provision of a means for the upright operating
staff to view of the patients eyes and temple area around the
eye, through the in line ocular and chin apertures **29** and **37**.
16 Normally the doctor or staff member wishing to view the
patient's eyes area adjacent to the eye temple area **74** or face
would have to stoop to an angle wherein they can be seen
through the in line apertures in the helmet casing **12** from the
side, or in some cases from below the operating table.
21 However, with the provision of a mirrored surface **72**,
operatively placed on the upper surface **67** of the mounting
plate **66**, the doctors and staff are afforded a means for a
continuous real time view while standing, of the patient's eyes
and mouth through the apertures **37** and **29** in the helmet casing

1 12. Should even more adjustability of the reflection be
desired so that certain staff in certain positions can see the
patient's eyes and mouth, a means for angular adjustment of the
mirrored surface 72 could be attached between the mounting
plate 66 and the mirrored surface 72 such as a ratchet 78 or
6 other conventional means for angular adjustment that will
provide the user with the ability to adjust the angle of the
mirrored surface 72 from substantially parallel to the mounting
plate 66 toward a position normal to the mounting plate 66.
The mirrored surface 72 with the means for angular adjustment
11 thus may be positioned to an infinite number of angles between
positions parallel and normal to the mounting plate 66. Such
adjustment provides substantial utility to the operating room
staff and doctors by allowing them to adjust the mirrored
surface 72 to obtain the best possible view of the patient
16 through the in line apertures of the facial cushion 31 and
helmet casing 12.

Should additional enhancement of patient viewing be
desired, the addition of the optional illumination means in the
current best mode in the form of light 76 which further
21 enhances the reflected view in the mirrored surface 72 by
illumination of the patient's facial features which reflect in
the mirrored surface 72. The illumination means could be a
conventional light bulb, a light emitting diode, or other
similar light sources and can be powered by conventional AC or

1 battery power that is readily available in the operating arena.

Construction of the one piece embodiment of the facial cushion **31** and the various options thereto, is best depicted in figure 9 and Figure 10. As shown from the top perspective view of figure 9, the indentations **68** to accommodate various sized
6 faces and facial structures are operatively positioned and provide excellent head support in the form of a forehead support **54**, cheek supports **55** and chin support **56**. The registration pins **73** protrude from the exterior surface **70** in positions to register the facial cushion **31** in operative
11 engagement with the leg axial passages **77** extending axially through the legs **60** of the one piece embodiment of the helmet casing **12**. Registered insertion of the facial cushion **31** into the helmet casing **12** is thus easily achieved by the in line cooperative engagement of the registration pins **73** with the
16 axial passages **77** in the legs **60**. Of course the other aforementioned means of registration of the facial cushion **31** with the helmet casing **12** might also be used including the lip **71**, adhesive **65**, or frictional engagement of the exterior surface **70** of the facial cushion **31** with the interior surface
21 of the helmet casing **12**. In cases where the additional utility of the helmet casing **12** encompassing the facial cushion **31** is not required the facial cushion **31** could be used alone in a frictional engagement with the surface of the table surface **64**.

1 Figures 11 and 12 provides a bottom perspective view and a
top perspective view respectively, of the one piece embodiment
of the helmet casing **12**. As shown, the legs **60** contain the
axial passageway **77** therein communicating with an leg aperture
63 at each end for registered engagement of the molded
6 registration pins **73**. The elongated casing ocular aperture **37**
in the one piece casing extends across the bottom and up both
sides of the one piece helmet casing **12**, and communicates with
the chin aperture **29** to form a single large "t" or figure eight
shaped aperture which registers in an in-line relationship with
11 a similar shaped and slightly larger aperture in the one piece
facial cushion **31**. Also depicted are a pair of optional tube
passageways **50** providing communication to the interior of the
helmet casing **12** through axial tube passages **52** therein.

A preferred embodiment of the mounting plate **66** component
16 is depicted in figures 13 and 14. The mounting plate **66** in the
current best embodiment is constructed of rigid plastic such as
polycarbonate which is substantially transparent. A plurality
of couplings **62** are attached to the upper surface **67** of the
mounting plate **66** to provide the registered mount for the legs
21 **60** of the helmet casing **12**. In this embodiment, rather than
having the mirrored surface **72** on the upper surface **67** of the
mounting plate **66** the mirrored surface **72** is adhered to the
bottom surface **83** of the mounting plate **66**. Adhering the
mirrored surface **72** to the mounting plate bottom surface **83**

1 facing upward toward the top surface, allows the mirrored
surface 72 to provide the desired reflection of the patients
face through the substantially transparent plastic material of
the mounting plate 66 while concurrently protecting the
mirrored surface 72 from scratching. In this embodiment the
6 mirrored surface 72 may be adhered to the bottom of the
mounting plate 66 by using mirror attached into an indent in
the bottom surface 83 or by applique of a metalized or
reflective surface to the bottom surface 83 such that when
viewed through the substantially transparent material making up
the mounting plate 66 from the upper surface 67 a reflection is
11 provided. The depicted optional outwardly biased conventional
plunger ball 85 would provide additional stability to the
couplings 62 in their cooperating engagement with the legs 60.

Additional utility during procedures where the temperature
16 of the patient is a concern is provided by the optional
removably attachable means for heating the head of the patient.
In the current best embodiment the means for heating the head
of the patient is provided by a removably attachable heating
blanket 87 as depicted in figure 15. The heating blanket is
21 removably attachable to the helmet casing 12 using biased clip
90 which is spring loaded and attaches to an upper edge of the
helmet casing 12. The heating blanket 87 provides heat using a
resistive element 92 which heats the blanket body 93 when power
from an electrical power source 94 is communicated thereto

1 through conventional wires **96**. The heat is distributed evenly
by the serpentine arrangement of the resistive element **92** thus
avoiding hot spots. Control of the amount and duration of heat
would be provided by a conventional thermostat **98** engagement
with the resistive element **92** to break the circuit when the
6 desired temperature is obtained. The wires **96** might also be a
flat strip style wire that is applliques to the exterior surface
70 of the helmet casing **12** and an interface on the clip **90** such
that attaching the clip **90** to the helmet casing **12** would also
provide power to the blanket **87** through the interface in the
clip **90**. Alternatively, in some cases it may be more
11 advantageous to attach the resistive element **92** by affixing it
or appliqueing it to the interior surface of the helmet casing
12 in between the facial cushion **31** and the helmet casing **12**
where it would work in the aforementioned fashion but provide
16 heat to the face of a prone patient or the back of the head of
a supine patient using the disclosed device.

While all of the fundamental characteristics and features
of the protective cushion and cooperatively engageable helmet
casing for anesthetized patient have been shown and described,
21 it should be understood that various substitutions,
modifications, and variations may be made by those skilled in
the art without departing from the spirit or scope of the
invention. Consequently, all such modifications and variations
are included within the scope of the invention as defined by
26 the following claims.

What is claimed is:

1. A protective helmet apparatus for providing patient cranial support during surgery, which may be assembled from a plurality of cooperatively engageable components of differing dimensions for achieving optimum fit and pressure diffusion upon face of the intended helmet wearer comprising:

Sub
(91) a cushion, said cushion having a front portion and two sidewalls extending upward from said front portion, said cushion having a interior surface and an exterior surface;

said interior surface of said cushion dimensioned to accommodate the facial structure of a human being;

at least one cushion ocular aperture in said cushion communicating laterally across said front portion and continuing up at least one of said sidewalls, said ocular aperture providing communication between said interior surface and said exterior surface;

a viewing passage formed by said ocular cushion aperture, said viewing passage providing a view through at least one of said sidewalls, wherein the eye and facial temple area and the eye of a patient wearing said cushion while in the prone position, may be seen through said viewing passage from a position adjacent to at least one of said sides. WA

2. The device as in claim 1 wherein said exterior surface of said cushion dimensioned for cooperative registered engagement with the interior of a helmet casing whereby said cushion is removably positionable on one of a helmet casing or a mounting surface in a position to provide support to the head of a patient undergoing surgery.

3. The protective helmet apparatus as defined in claim 2 further comprising:

a helmet casing for use in combination with said cushion, said helmet casing having a casing front wall and two casing sidewalls, each of said sidewalls attached at a first edge to said front wall extending generally vertically therefrom to an upper edge of said sidewalls, said helmet casing having a casing interior surface and a casing exterior surface;

means for registered cooperative engagement of said cushion with said helmet casing;

at least one casing ocular aperture in said helmet casing communicating between said casing interior surface and said casing exterior surface, said casing ocular aperture shaped substantially similar to said cushion ocular aperture, and positioned in said helmet casing to align with said cushion ocular aperture when said cushion is in said registered cooperative engagement with said helmet casing, whereby said viewing passage extends through said casing ocular aperture when said cushion is in registered cooperative engagement with said helmet casing; and

means for removable attachment of said helmet casing to a fixed position on a mounting surface.

4. The protective helmet apparatus as defined in claim 3 wherein said means for registered cooperative engagement of said cushion with said helmet casing comprises one or a combination of means for registered cooperative engagement from

a group consisting of, said casing interior surface dimensioned for frictional engagement with said exterior surface of said cushion, adhesive, a lip positioned on said cushion in a position for operative engagement with the upper edges of said sidewalls, and registration pins affixed to said exterior surface of said cushion cooperatively engageable with registration apertures located in said interior surface of said helmet casing.

5. The protective helmet apparatus as defined in claim 4 wherein said means for registered cooperative engagement of said cushion with said helmet casing is a plurality of said registration pins extending from the exterior surface of said cushion, said registration pins dimensioned to cooperatively engage axial passages communicating through said casing.

6. The protective helmet apparatus as defined in claim 3 wherein said means for attachment of said helmet casing to said mounting surface comprises a plurality of legs extending from the exterior surface of said helmet casing, the distal ends of said plurality of legs configured for cooperative engagement with a mount, said mount attachable to said mounting surface.

7. The protective helmet apparatus as defined in claim 3 further comprising:

a chin aperture communicating through said front portion of said cushion, said chin aperture communicating between said interior surface and said exterior surface of said cushion, and

a nasal cavity defined by the perimeter of said chin aperture and the wall surface of said chin aperture.

8. The protective helmet apparatus as defined in claim 7 further comprising a casing chin aperture in said casing front wall said casing chin aperture communicating between said casing interior surface and said casing exterior surface, said casing chin aperture shaped substantially similar in shape to said cushion chin aperture and positioned to align with said cushion chin aperture when said cushion is in said registered engagement with said helmet casing; and

said nasal cavity communicating from said interior surface of said cushion to said exterior surface of said casing thereby forming a tube passageway.

9. The protective helmet apparatus as defined in claim 8 wherein said cushion chin aperture and said cushion ocular aperture communicate to form a single cushion aperture communicating through said cushion,

said casing chin aperture and said casing ocular aperture communicating to form a single casing aperture substantially the same in shape as said single cushion aperture; and

said single cushion aperture and said single casing aperture are substantially in line when said cushion placed in said cooperative engagement with said helmet casing.

10. The protective helmet apparatus as defined in claim 3 further comprising a means for elevation of said helmet casing above said mounting surface.

11. The protective helmet apparatus as defined in claim 6 wherein said mount comprises

a mounting plate, said mounting plate having an upper surface and a lower surface;

means of attachment of said lower surface to a determined position on said mounting surface; and

a plurality of couplings affixed to said upper surface of said mounting plate in positions to register with said distal ends of said plurality of legs, said couplings dimensioned for cooperative engagement with the distal end of said legs, whereby said legs may be removably mounted to said couplings in a cooperative registered engagement therewith.

12. The protective helmet apparatus as defined in claim 3 wherein said cushions are in a kit of variably sized cushions to accommodate a variety of head sizes each of said cushions in said kit configured for cooperative registered engagement with said helmet casing whereby said combination of said helmet casing and said cushion may be fitted to a variety of different sized patients having different physical characteristics and may be assembled from said collection of interchangeable cushions.

13. The protective helmet apparatus as defined in claim 10 wherein said means for elevation of said helmet casing above said mounting surface comprises a plurality leg extensions chosen from a kit of said leg extensions of varying length, each of said leg extensions configured for cooperative engagement between the distal end of said legs and said couplings, whereby the resulting elevation of said helmet above said mounting surface may be adjusted using longer or shorter leg extensions.

14. The protective helmet apparatus as defined in claim 11 wherein said mount additionally comprises, a mirrored surface affixed to said mounting plate, thereby providing a means for upright individuals standing adjacent to said protective head apparatus to view the ocular area of the patients face reflected in the mirrored surface by looking downward at said mirrored surface.

15. The protective helmet apparatus as defined in claim 13 further comprising a means for angular adjustment of said mirrored surface in relation to said mounting plate, whereby the angle of said mirrored surface may be adjusted to the optimum angle for viewing said ocular area.

16. The protective helmet apparatus as defined in claim 13 further comprising a means for illumination, said means for illumination attached to one of said helmet casing or said mounting plate, said means for illumination positioned to

illuminate the face of said patient.

17. The protective helmet apparatus as defined in claim 3 further comprising:

means for heating the head of the patient attachable to said helmet casing.

18. The protective helmet apparatus as defined in claim 17 wherein said means for heating the head of a patient, is an electrical resistive heating element, attached to the interior surface of said helmet casing.

19. The protective helmet apparatus as defined in claim 15 herein said means ND for heating the head of a patient is an electrical resistive heating element mounted on a blanket which is attachable to one of said upper edges of said side walls, whereby said blanket may be folded over the patients head when said head is operatively occupying said protective helmet apparatus.

20. The protective helmet apparatus as defined in claim 3 wherein said helmet casing is constructed of substantially transparent material thereby affording a view into the ocular cushion aperture through the sidewall and front wall surfaces of the helmet casing.

53

21. The protective helmet apparatus as defined in claim 3 additionally comprising at least one tube passageway communicating through said helmet casing.

22. The protective helmet apparatus as defined in claim 3 wherein said helmet casing is adhered to said exterior surface of said cushion into a unitary structure.

Att
96 7

Attorney's Docket No. _____

COMBINED DECLARATION AND POWER OF ATTORNEY(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION OR CIP)

As a below-named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

☒ original☐ design☐ supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

☐ national stage of PCT

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

☐ divisional☐ continuation☒ continuation-in-part (C-I-P).**INVENTORSHIP IDENTIFICATION**

WARNING: If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

PROTECTIVE CUSHION AND COOPERATIVELY ENGAGEABLE HELMET CASING FOR
ANESTHETIZED PATIENT

SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b) or (c))

(a) [X] is attached hereto.

(b) ☐ was filed on _____ as

☐ Serial No. _____ or

☐ Express Mail No., as Serial No. not yet known _____
and was amended on _____ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

(c) ☐ was described and claimed in PCT International No. _____ filed on _____ and as amended under PCT Article 19 on _____ (if any).

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations § 1.56,

(also check the following items, if desired)

☐ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ In compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) ☐ no such applications have been filed.
- (e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

COUNTRY (or indicate if PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER

FILING DATE

____ / _____

CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S)
UNDER 35 U.S.C. 120



The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

DONN K. HARMS
4565 Ruffner Street, Ste. 200
San Diego, CA 92111

REG. NO. 38,911

FRANK D. GILLIAM
4565 Ruffner Street, Ste. 200
San Diego, CA 92111

REG NO. 26,548

JOHN R. DUNCAN
4565 Ruffner Street, Ste. 200
San Diego, CA 92111

REG NO. 22,276

(check the following item, if applicable)

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

DONN K. HARMS
4565 Ruffner Street, Ste. 200
San Diego, CA 92111

DIRECT TELEPHONE CALLS TO:

DONN K. HARMS
Tel (619) 292-0901
Fax (619) 292-0905

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE (S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor WILLIAM MAZZEI, M.D.
Inventor's signature *W. J. Mazzei*
Date 04/15/00 Country of Citizenship United States of America
Residence 9707 Caminito Suelto, San Diego Calif 92131
Post Office Address 9707 Caminito Suelto, San Diego, Calif 92131

Full name of second joint inventor, if any GREGORY P. JORDAN
Inventor's signature *G. P. Jordan*
Date 04/15/00 Country of Citizenship United States
Residence 2695 Coventry Road, Carlsbad, California 92008
Post Office Address 2695 Coventry Road, Carlsbad, California 92008

Full name of third joint inventor, if any AN P. VU
Inventor's signature *AN P. Vu*
Date 04/15/00 Country of Citizenship United States
Residence 320 Pomelo Drive, Vista, California 92083
Post Office Address 320 Pomelo Drive, Vista, California 92083

(check proper boxes) for any of the following added page(s)
that form a part of this declaration)

☐ **Signature** for fourth and subsequent joint inventors. Number of
pages added _____.

* * *

☐ **Signature** by administrator(trix), executor(trix) or legal
representative for deceased or incapacitated inventor.
Number of pages added _____.

* * *

☐ **Signature** for inventor who refuses to sign or cannot be reached by
person authorized under 37 CFR 1.47.
Number of pages added _____.

* * *

☐ Added page for **signature** by one joint inventor on behalf of
deceased inventor(s) where legal representative cannot be
appointed in time. (37 CFR 1.47)

* * *

☐ Added pages to combined declaration and power of attorney for
divisional, continuation, or continuation-in-part (C-I-P)
application.

☐ Number of pages added _____.

* * *

☐ Authorization of attorney(s) to accept and follow instructions
from representative.

If no further pages form a part of this Declaration then end this
Declaration with this page and check the following item

[XX] This declaration ends with this page

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit:

Examiner:

Inventor(s): WILLIAM MAZZEI; GREGORY P. JORDAN; AN B. VU;

Serial Number:

Filed: April 9, 2000

For:

Protective Cushion and Cooperatively Engageable Helmet Casing for Anesthetized Patient

Patent No.

Issued:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) AND 1.27(b)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention described in

- ☒ the specification filed herewith.
- ☐ the application whose serial number is set forth above.
- ☐ the patent set forth above.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not likewise be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Signature William Mazzei
William Mazzei, M.D.

Date: April 5, 2000

Signature Gregory Jordan
Gregory Jordan

Date: April 5, 2000

Signature _____
An B. Vu

Date: April 5, 2000

ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: "In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112." 37 CFR 1.78(a).

NOTE: "In addition the prior application must be (1) complete as set forth in § 1.51, or (2) entitled to a filing date as set forth in § 1.53(b) and include the basic filing fee set forth in § 1.16; or (3) entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(f) within the time period set forth in § 1.53(d)." 37 CFR 1.78(a).

17. Relate Back

WARNING: If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

(complete the following, if applicable)

☐ Amend the specification by inserting, before the first line, the following sentence:

A. 35 U.S.C. 119(e)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending provisional applications must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior provisional application, identifying it as a provisional application, and including the provisional application number (consisting of series code and serial number)." 37 C.F.R. § 1.78(a)(4).

() "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____ / _____	_____ "
_____ / _____	_____ "
_____ / _____	_____ "

B. 35 U.S.C. 120, 121 and 365(c)

NOTE: "Any nonprovisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross-references to other related applications may be made when appropriate. (See § 1.14(b))." 37 C.F.R. § 1.78(2).

- ☒ "This application is a
- ☐ continuation
 - ☒ continuation-in-part
 - ☐ divisional

of copending application(s)

- ☒ application number 09/080,975 filed on 5/19/98.
- ☐ International Application _____ filed on _____ and which designated the U.S."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

- ☐ "The nonprovisional application designated above, namely application _____ / _____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s):

APPLICATION NO(S):

FILING DATE

_____ / _____	_____ "
_____ / _____	_____ "
_____ / _____	_____ "

NOTE: The deadline for entering the national phase in the U.S. for an international application was clarified in the Notice of April 28, 1987 (1079 O.G. 32 to 46) as follows:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectively. These periods have been placed in the rules as paragraph (h) of § 1.494 and paragraph (i) of § 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

country	appln. no.	filed on
---------	------------	----------

The certified copy(ies) has (have)

- ☐ been filed on _____, in prior application 0 / _____, which was filed on _____.
- ☐ is (are) attached.

WARNING: The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

- A.** ☐ Extension of time in prior application

(This item must be completed and the papers filed in the prior application, if the period set in the prior application has run.)

- ☐ A petition, fee and response extends the term in the pending prior application until _____.
- ☐ A copy of the petition filed in prior application is attached.

- B.** ☐ Conditional Petition for Extension of Time in Prior Application

(complete this item, if previous item not applicable)

- ☐ A conditional petition for extension of time is being filed in the pending prior application.
- ☐ A copy of the conditional petition filed in the prior application is attached.

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

NOTE: "If the continuation, continuation-in-part, or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation, continuation-in-part, or divisional application." 37 CFR 1.62(a) [emphasis added]. (dealing with the file wrapper continuation situation).

NOTE: "In the case of a continuation-in-part application which adds and claims additional disclosure by amendment, an oath or declaration as required by § 1.63 must be filed. In those situations where a new oath or declaration is required due to additional subject matter being claimed, additional inventors may be named in the continuing application. In a continuation or divisional application which discloses and claims only subject matter disclosed in a prior application, no additional oath or declaration is required and the application must name as inventors the same or less than all the inventors in the prior application." 37 CFR 1.60(c) (dealing with the continuation situation).

(complete applicable item (a), (b) and/or (c) below)

- (a) ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

☐ the same.

- ☒ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

- (b) ☒ This application discloses and claims additional disclosure by amendment and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

- ☒ the following additional inventor(s) have been added:

GREGORY P. JORDAN, AN B. VU
(type name(s) of inventor(s) to be added)

- (c) The inventorship for all the claims in this application are

☒ the same.

☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

21. Abandonment of Prior Application (if applicable)

- ☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: "The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application." MPEP, § 706.07(b).

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.

(check the next item, if applicable)

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. Small Entity (37 CFR § 1.28(a))

- ☒ Applicant has established small entity status by the filing of a verified statement in parent application 69 / 080,925 on 05/19/98.
- ☐ A copy of the verified statement previously filed is included.

WARNING: "Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. Applications filed as continuations, divisions or continuations-in-part of a parent application must include a reference to a verified statement filed in the parent application if status as a small entity is still proper and desired." 37 CFR § 1.28(a).

24. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

- ☐ A notification of the filing of this
(check one of the following)
- ☐ continuation
 - ☐ continuation-in-part
 - ☐ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

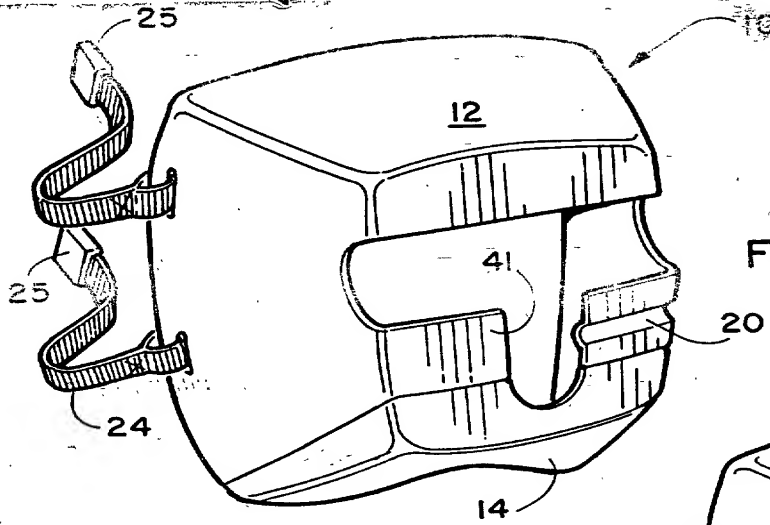


FIGURE 1

FIGURE 2

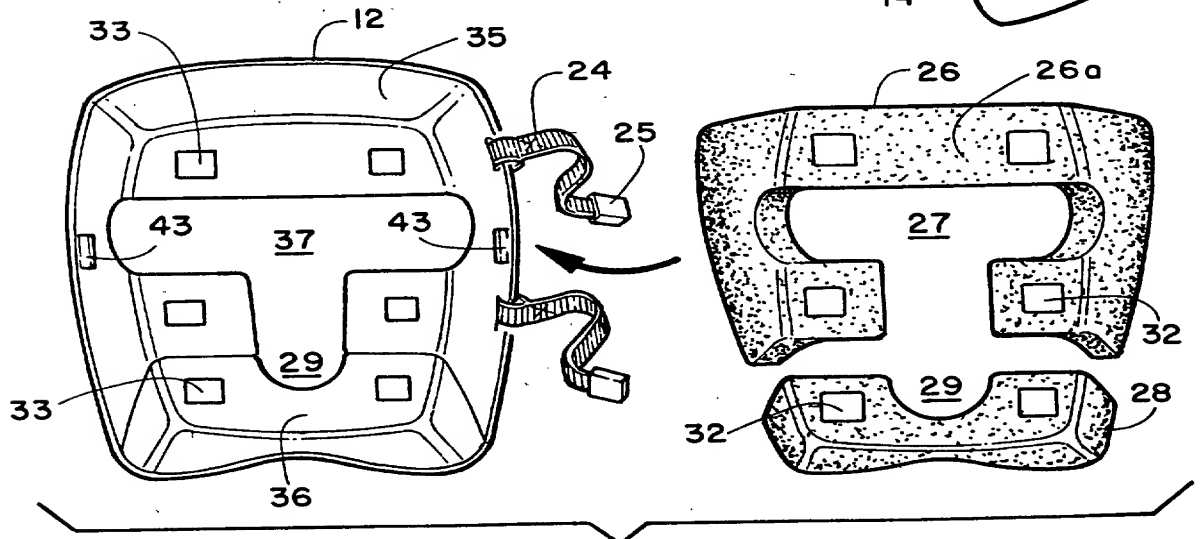
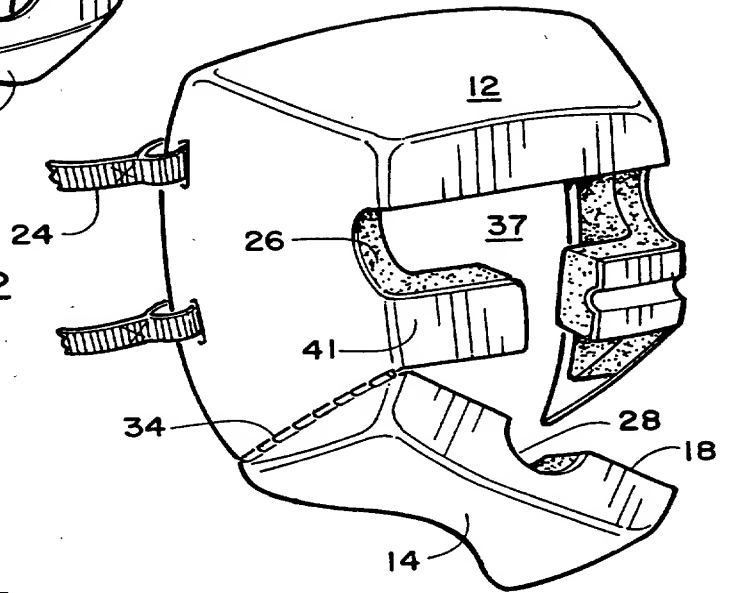


FIGURE 3

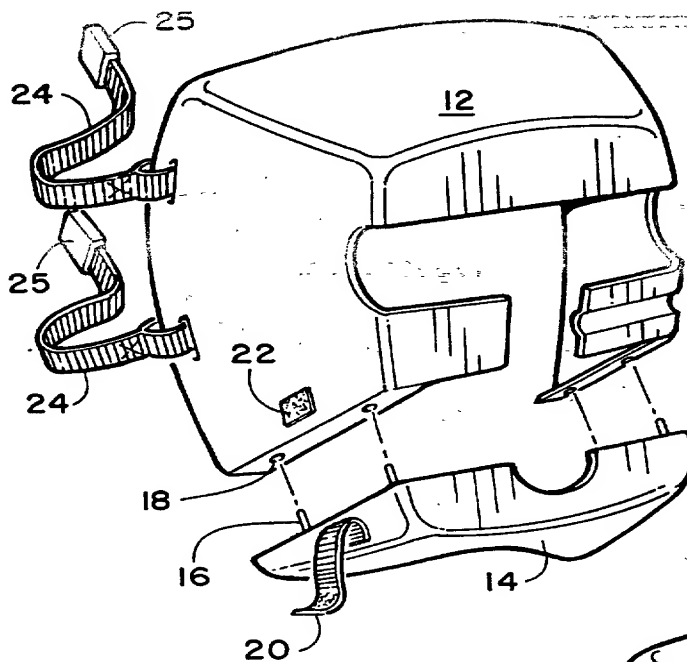


FIGURE 4

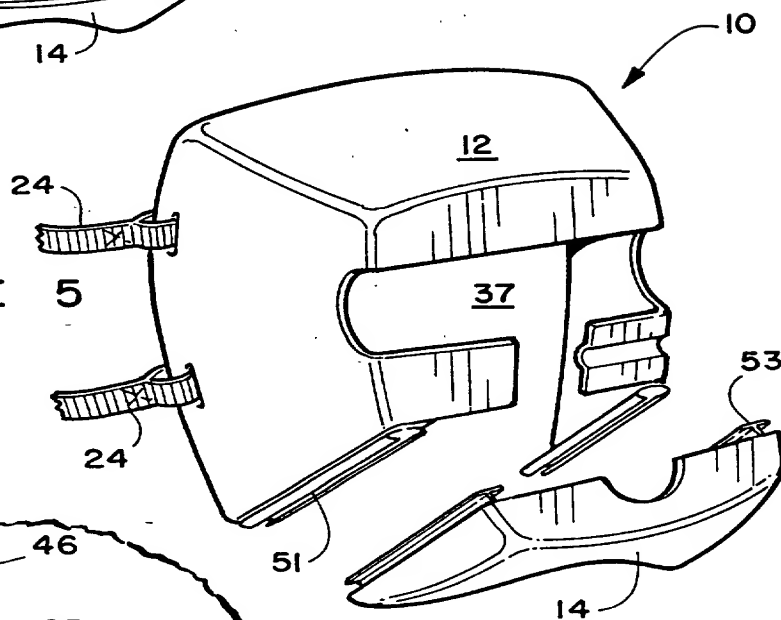


FIGURE 5

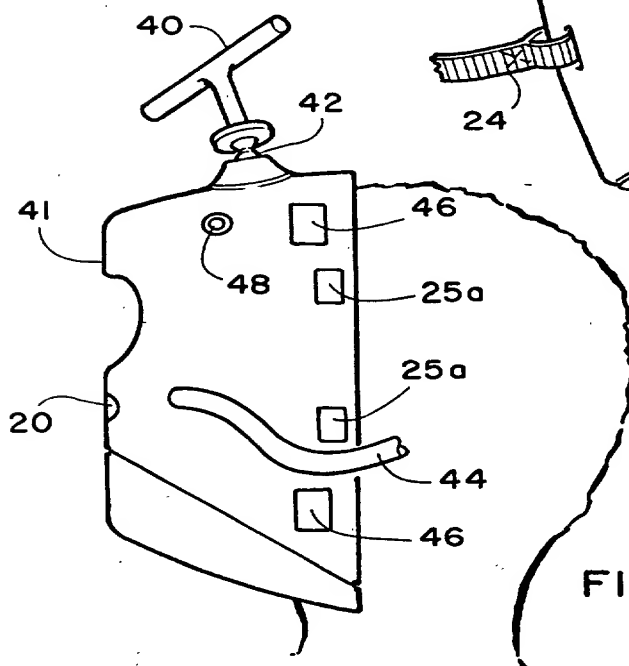


FIGURE 6

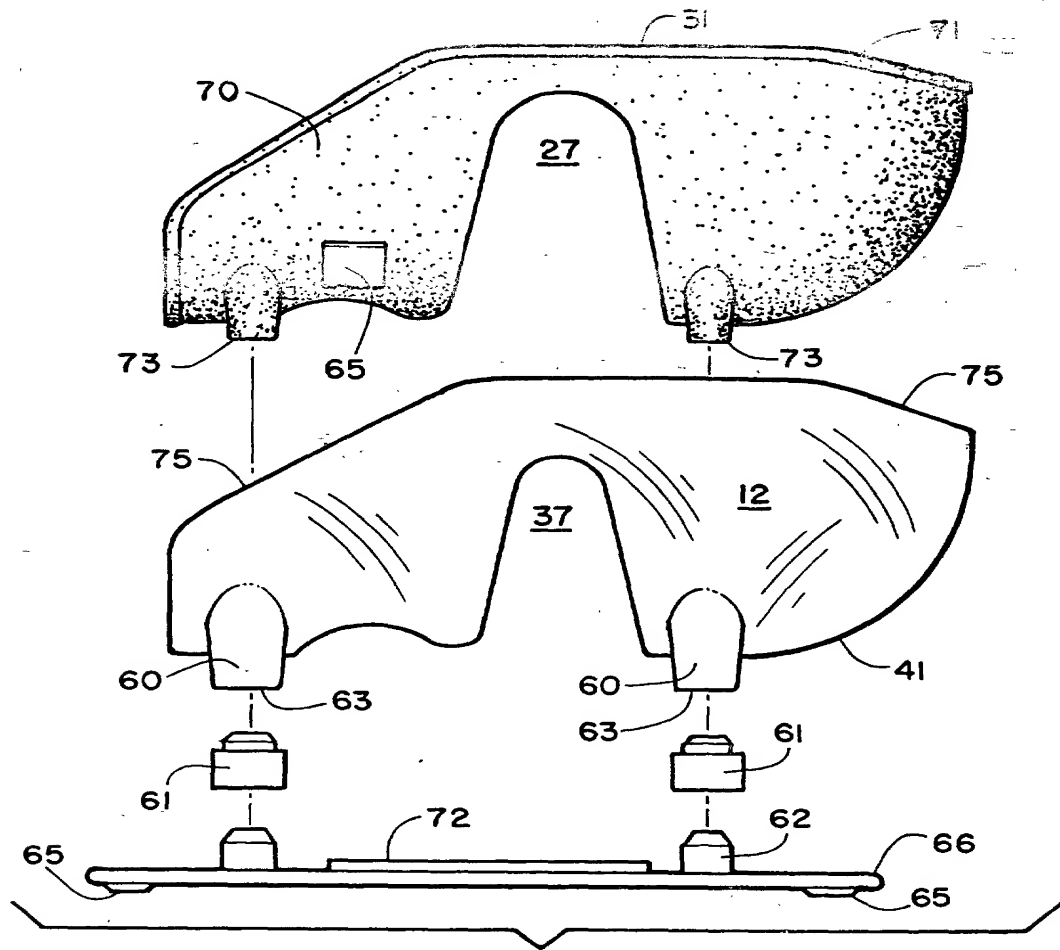


FIGURE 7

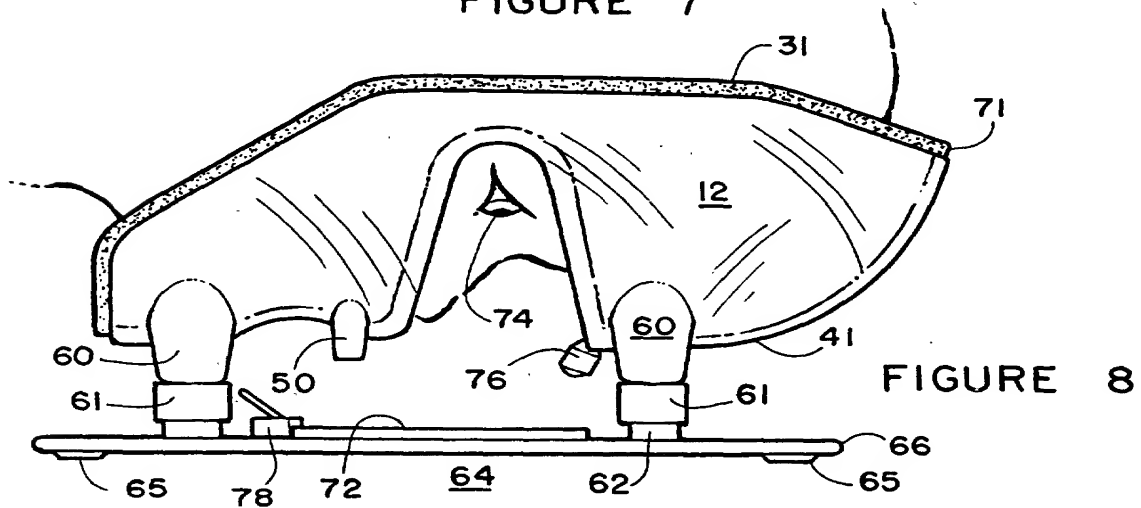


FIGURE 8

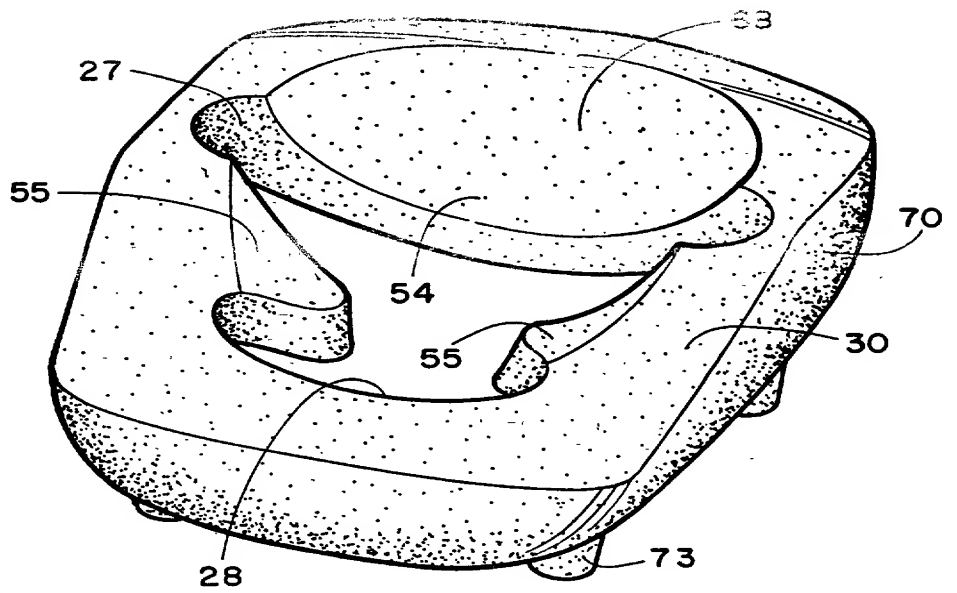


FIGURE 9

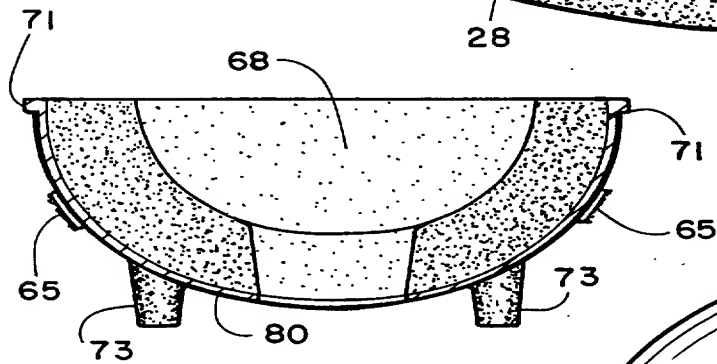


FIGURE 10

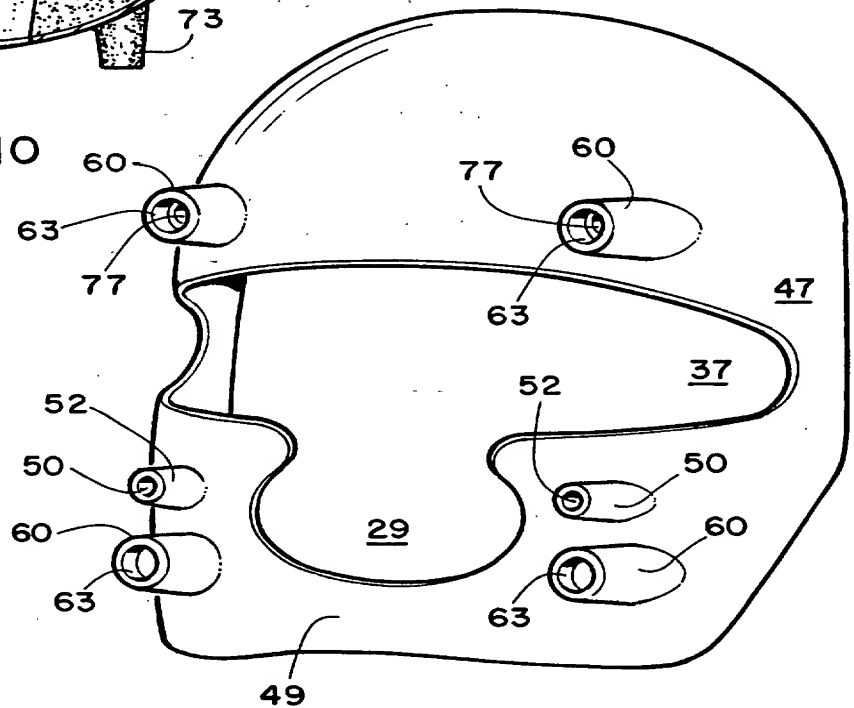


FIGURE 11

006070-16/54500

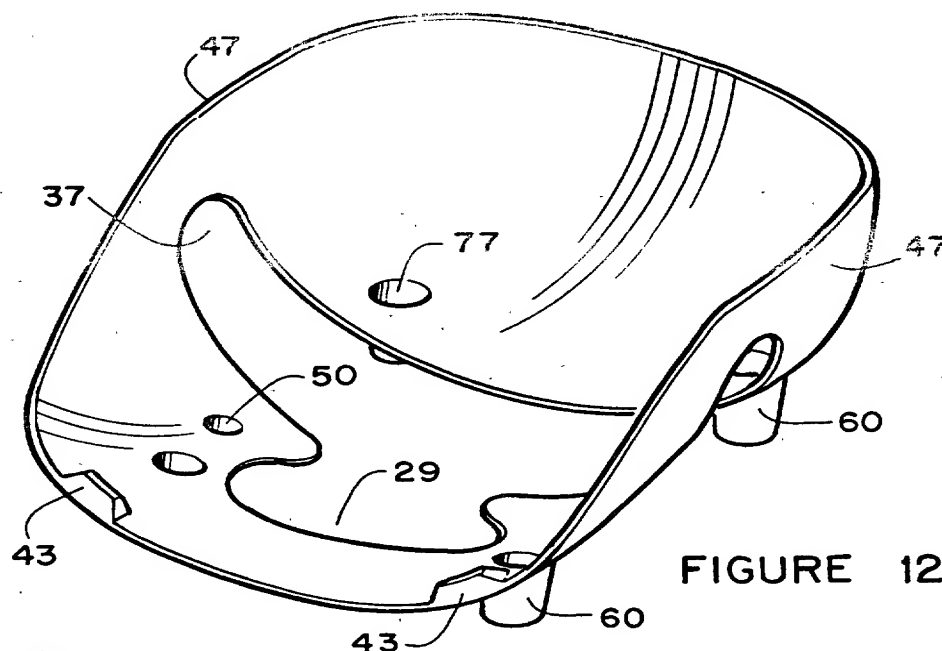


FIGURE 12

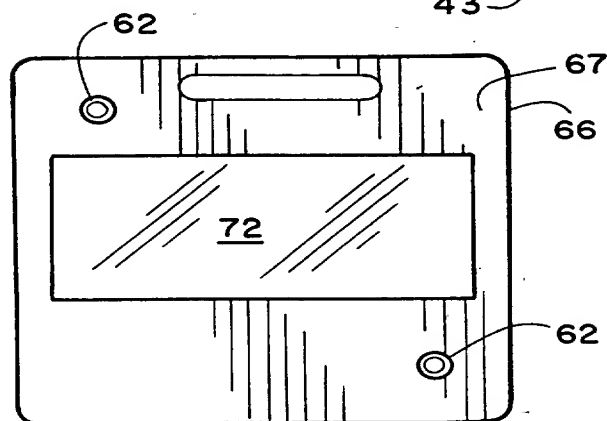


FIGURE 14

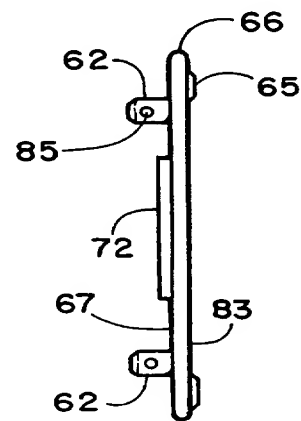


FIGURE 13

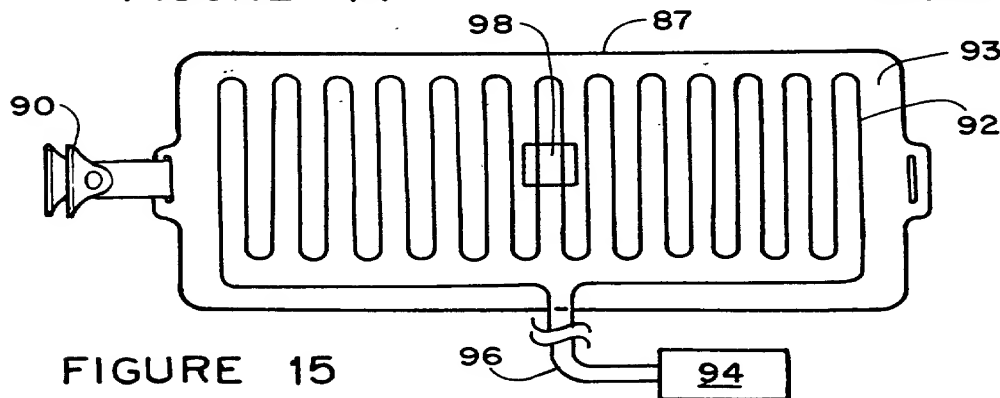


FIGURE 15

006070-16/51560

Box Patent Application
Commissioner of Patents and Trademarks
Washington, D.C. 20231

PATENT

Docket No.

204/ CIP

04-71-00

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): WILLIAM MAZZEI, M.D.; GREGORY P. JORDAN; AN B. VU;

WARNING: Patent must be applied for in the name(s) of the actual inventor(s) .37CFR 1.41 and 1.53(b).

For (title): **PROTECTIVE CUSHION AND COOPERATIVELY ENGAGEABLE HELMET CASING FOR ANESTHETIZED PATIENT**

1. Type of Application

This new application is for a(n) (check one applicable item below):

☒ Original

☐ Design

☐ Plant

WARNING: Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

☐ Divisional

☐ Continuation

☒ Continuation-in-part (CIP)

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date - APRIL 9, 2000 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EJ200784785US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231

Donn. K. Harms

(Type or print name of person mailing paper)

(Signature of person mailing paper)

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

2. Benefit of Prior U.S. Application(s) (35 USC 120)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

[X] The new application being transmitted claims the benefit of prior U.S. applications(s) and enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. Papers Enclosed Which Are Required For Filing Date Under 37 CFR 1.53(b) (Regular) or 37 CFR 1.53 (Design) Application

47 Pages of specification
8 Pages of claims
2 Pages of Abstract
5 Sheets of drawing

[XX] formal
[] informal

WARNING:

DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. **Only one copy is required or desired.** Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia such as the serial number, group and unit, title of the invention, attorney's docket number, inventor's name, number of sheets, etc., not to exceed 2 3/4 inches (7.0 cm.) in width may be placed in a centered location between the side edges within three fourths inch (19.1 mm.) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 57-62).

4. Additional papers enclosed

- ☐ Preliminary Amendment
- ☐ Information Disclosure Statement (37 CFR 1.98)
- ☐ Form PTO-1449
- ☐ Citations
- ☐ Declaration of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments

5. Declaration or oath

[XX] Enclosed
executed by (check **all** applicable boxes)

[XX] inventor(s).

☐ legal representative of inventor(s). 37 CFR 1.42
or 1.43

☐ joint inventor or person showing a proprietary
interest on behalf of inventor who refused to sign
or cannot be reached.

☐ this is the petition required by 37 CFR 1.47 and
the statement required by 37 CFR 1.47 is also
attached. See item 12 below for fee.

☐ Not enclosed.

WARNING: Where the filing is a completion in the U.S. of an International Application
but where a declaration is not available or where the completion of the U.S.
application contains subject matter in addition to the International
Application, the application may be treated as a continuation or continuation-
in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION
TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

☐ Application is made by a person authorized under 37 CFR
1.41 (C) on behalf of all the above named inventor(s).
(The declaration or oath, along with the surcharge required by 37 CFR
1.16(e) can be filed subsequently).

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR
1.41(c) and 1.53(b).

☐ Showing that the filing is authorized. (Not required
unless called into question. 37 CFR 1.41(d).)

6. Inventorship Statement

WARNING: If the named inventors are each not the inventors of all the claims, an
explanation, including the ownership of the various claims at the time the
last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

[X] The same

or

☐ Are not the same. An explanation, including the ownership of
the various claims at the time the last claimed invention was
made,

☐ is submitted

☐ will be submitted.

7. **Language**

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$130.00 required by 37 CFR 1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

☐ English

☐ non-English

☐ the attached translation is a verified translation. 37 CFR 1.52(d).

8. **Assignment**

☐ An assignment of the invention to Dupaco Corporation

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

[X] will follow

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the supplication and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

9. **Certified Copy**

Certified copy(ies) of application(s)

(country)

(appln. no.)

(filed)

(country)

(appln. no.)

(filed)

from which priority is claimed

☐ is(are) attached.

☐ will follow.

NOTE: The¹ foreign application forming the basis for the claim for priority **must** be referred to in the **oath** or **declaration**. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation 37 CFR 1.16)

A. ☐ Regular application

CLAIMS AS FILED			
Number filed	Number Extra	Rate	Basic Fee \$690.00
Total Claims -20=	1	x \$ 18.00	36.00
Independent Claims -3=		x \$ 72.00	0
Multiple Dependent Claim(s), if any		\$260.00	0

- ☐ Amendment canceling extra claims enclosed
- ☐ Amendment deleting multiple dependencies enclosed
- ☐ Fee for extra claims is not being paid at this time

NOTE: If the fees for extra claims are not paid on filing, they must be paid, or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$ 726.00

B. ☐ Design application
(\$310.00--37 CFR 1.16(f))

Filing Fee Calculation \$ _____

C. ☐ Plant application
(\$510.00--37 CFR 1.16(g))

Filing fee Calculation \$ _____

11. Small Entity Statement(s)

[XX] Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached.

Filing Fee Calculation (50% of A or B above) \$ 363.00

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

12. Request for International-Type Search (37 CFR 1.104(d) (complete, if applicable))

☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made At This Time

☐

Not Enclosed

☐

No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

[XX] Enclosed

[XX] basic filing fee

\$363.00

☐

recording assignment

\$

(\$40.00; 37 CFR 1.21(h)(1))

☐

petition fee for filing by other than the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached (\$130.00; 37 CFR 1.47 and 1.17(h))

\$

☐

for processing an application with a specification in a non-English language. (\$130.00; 37 CFR 1.52(d) and 1.17(k))

\$

☐

processing and retention fee

\$

\$130.00; 37 CFR 1.53(d) and 1.21(l))

☐

fee for international-type search report (\$40.00; 37 CFR 1.21(e))

\$

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or the processing and retention fee of \$ 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed

\$ 363.00

14. Method of Payment of Fees

☐

Check in the amount of \$363.00

☐

Charge Account No. in the amount of \$
A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should **not** be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorize

[XX] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 07-1338 .

[XX] 37 CFR 1.16(a), (f) or (g) (filing fees)

[XX] 37 CFR 1.16 (b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extension of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G.27)

☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b)).

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.31(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application...prior to paying, or at the time of paying...issue fee". From the wording of 37 CFR 1.28(b):(a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

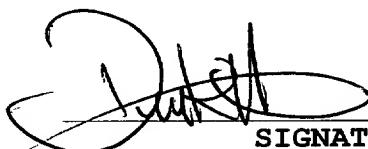
16. Instructions As To Overpayment

[XX] credit Account No. 07-1338

☐ refund

Reg. No. 38,911

Tel. No. (619) 292-0901
Fax No. (619) 292-0905



SIGNATURE OF ATTORNEY

DONN K. HARMS
4565 Ruffner Street, Ste. 200
San Diego, California 92111

[x] **Incorporation by Reference of added pages**

Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

[x] Plus Added Pages For New Application Transmittal Where Benefit Of Prior U.S. Application(s) Claimed

Number of pages added 5

☐ Plus Added Pages For Papers Referred To In Item 4 Above

Number of pages added _____

☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added _____

☐ **Statement Where No Further Pages Added**

If no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item

[] This transmittal ends with this page.